

REMARKS

Reconsideration and withdrawal of the objections to and rejections of the present application are respectfully requested in view of the remarks herein.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1, 4-6 and 8-38 are pending, with claims 26-38 withdrawn from consideration. By this paper claims 14 and 15 have been amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. No new matter is added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and the originally-filed claims and the claims herewith are and were in full compliance with the requirements of 35 U.S.C. §112. The claims amended herein are not amended for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, the amendments to the claims are presented simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel.

II. THE OBJECTIONS TO THE CLAIMS ARE OVERCOME

Claim 15 was objected to because it depended from a rejected claim. As described below, claim 1 (from which claim 15 depends) is allowable over the cited prior art, and consequently the objection to claim 15 is not proper. However, in order to expedite prosecution, claim 15 is hereby rewritten in independent form, thereby rendering this objection moot.

III. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME

Claim 14 was rejected for allegedly being indefinite for failing to provide units for the weight of the polyhydroxypolymer. This rejection is respectfully traversed. Claim 14 does not simply recite “weight” but instead recites “molecular weight”. Molecular weight by definition has no units, since molecular weight is a relative measure based on the ratio of the weight of a given molecule and the weight of an equimolar amount of carbon 12. However, molecular weight is often expressed using the unit of Daltons. In order to expedite prosecution, claim 14 is

hereby amended to recite the molecular weight as “500 Daltons”, thereby overcoming this rejection.

III. THE REJECTIONS UNDER 35 U.S.C. §102 ARE OVERCOME

A. Cheronis et al.

Claims 1, 4-6, 8-14 and 16-24 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,573,916 to Cheronis *et al.* (“Cheronis”). This rejection is respectfully traversed.

It is respectfully asserted that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barent Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Although the specification of Cheronis states that “[t]he specific conjugation method used may vary depending upon the nature of the specific epitopes used and the type of carrier chosen” (Column 5, lines 45-48), Cheronis is only enabling, if at all, for conjugation of peptides to carriers via cysteine residues. The Detailed Description and Examples of Cheronis describe only conjugation of peptides to dextran via a cysteine residue. Thus, in Example 5 of Cheronis it is stated that “the “peptide was conjugated via an additional cysteine residue on its N terminus to the dextran backbone” (Column 9, lines 33-35). The fact that the peptides in Cheronis are coupled to a backbone via a cysteine residue necessarily means that the coupling occurs via a sulphur atom. This is in direct contrast to the coupling mechanism recited the rejected claims, all of which recite or require that the antigenic determinants are coupled to the carrier via nitrogen atoms.

Cheronis *et al.* fails to meet the requirements of 35 U.S.C. §102(b), as described above. In particular, Cheronis does not teach all of the elements of the rejected claims and does not enable the claimed invention. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

B. Chisari and Cerny

Claims 1, 4-6, 8-10, 13 and 16-25 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,709,995 to Chrisari and Cerny (“Cerny”). This rejection is respectfully traversed.

The specification of Cerny states that a peptide may be coupled to a matrix at “*any suitable position, including N and C termini or points in between, depending on the availability of appropriate reactive groups in the side chains of the constituent amino acids of the polypeptide of interest*” (emphasis added). Cerny describes only a handful of suitable carriers, namely lipids, proteins, liposomes, and bovine serum albumin (Column 6, lines 62-64). Cerny provides no teaching or suggestion of conjugation methods that might be suitable for conjugation of peptides to activated polyhydroxypolymer carriers, and certainly provides no teaching or suggestion that all peptides, regardless of the reactive groups in their side chains, can be coupled to carriers via nitrogen atoms at their N-termini.

Cerny fails to meet the requirements of 35 U.S.C. §102(b), as described above. In particular, Cerny does not teach all of the elements of the rejected claims and does not enable the claimed invention. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

C. Chisari.

Claims 1, 4-6, 8-11, 13 and 16-25 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,780,036 to Chisari. This rejection is respectfully traversed.

Although the specification of Chisari does mention briefly that “*the peptide can be optionally flanked and/or modified at one or both of the N- and C-termini, as desired*” (see Column 2, lines 50 –51), the only modifications described include those designed to facilitate coupling via cysteine links, disulphide links, or thioether links (See Column 10, lines 28-55). Chisari fails to teach or suggest a coupling method by which peptides are coupled to a carrier via nitrogen atoms at the N-termini of the peptides.

Chisari fails to meet the requirements of 35 U.S.C. §102(b), as described above. In particular, Chisari does not teach all of the elements of the rejected claims and does not enable the claimed invention. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the amendments and remarks herewith, which are fully responsive to the rejections, the application is in condition for allowance. Consideration and entry of this paper, favorable reconsideration of the application and reconsideration and withdrawal of the objections to and rejections of the application, and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,
FROMMERM LAWRENCE & HAUG LLP

By:



Thomas J. Kowalski
Reg. No. 32,147
Angela M. Collison
Reg. No. 51,107
Telephone: (212) 588-0800
Facsimile: (212) 588-0500